

## REMARKS

Previously claims 14-21 were pending. In the instant amendment, claims 14, 15, 17, 18, 20 and 21 have been canceled, without prejudice. Claims 16 and 19 have been amended. New claims 22 and 23 have been added. After entry of the instant amendment, claims 16, 19, 20 and 21 will be pending and under consideration.

### I. AMENDMENT TO THE CLAIMS

Claims 14, 15, 17, 18, 20 and 21 have been canceled without prejudice to Applicants' right to pursue canceled subject matter in one or more related applications.

Claims 16 and 19 have been amended to be presented in an independent form.

New claims 22 and 23 are supported by the specification, for example, at page 3, lines 2-7, page 20, lines 32-34, and the claims as originally filed.

Applicants respectfully submit that the amendments to the claims are supported by the specification and claims as filed, and that no new matter has been added. Entry of the amendments to the claims is therefore kindly requested.

No amendment fee is believed to be due.

### II. OBJECTION TO CLAIMS 16 AND 19

The Patent Office objects to claims 16 and 19 as being dependent upon a rejected base claim, and states that these claims would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicants have amended claims 16 and 19 to be rewritten in independent form as suggest by the Patent Office. Accordingly, Applicants respectfully request that the objection to claims 16 and 19 be withdrawn.

### III. CLAIM REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

Claims 14-15, 17, 18 and 20-21 stand rejected under 35 U.S.C. § 112, first paragraph, allegedly for non-enablement. While Applicants do not agree with the propriety of the rejection, nonetheless the rejection of claims 14-15, 17, 18 and 20-21 under 35 U.S.C. § 112, first paragraph, is moot in view of the cancellation of these claims in the instant amendment. Applicants therefore respectfully request the withdrawal of the rejection of claims 14-15, 17, 18 and 20-21 under 35 U.S.C. § 112, first paragraph.

Office recites articles regarding the unpredictability of the art, which is merely one factor in the analysis of whether “undue experimentation” exists but ignores the guidance provided by the specification to those of skill in the art to make and use the claim.

In the instant application, the specification teaches a peptide designed from an alpha-1 region of HFE protein that provides the function of the normal naturally-occurring HFE protein in inhibiting cell-associated binding of transferrin. It is not the case that the “magic bullet” is yet to be found since the specification teaches a working example and provides guidance for making relevant conservative substitutions to the claimed compounds, for example, indicating critical residues such as tryptophan at position 11 and isoleucine at position 13 of SEQ ID NO: 1 (*see* page 27, lines 16-20, describing the effect of substituting tryptophan-11, and claims as originally filed in which isoleucine-13 is a non-substitutable residue in formula I). The specification further teaches that the peptides are designed from an alpha-1 region of HFE protein (*see* page 2, lines 16-17), thereby informing those of ordinary skill in the art that conservatively substituted peptides should mimic the secondary structure of the alpha-1 region of HFE protein. The specification provides guidance on methods of making peptides (pages 16-19), purifying peptides (pages 19-20), formulating and administering the compounds comprising the peptides of claims 22 and 23 (pages 21-23), effective dosages of the compounds to be administered (pages 23-24), and how to determine toxicity of the compounds (pages 24-25). Hence, Applicants respectfully submit that specification fully enables those of ordinary skill in the art to make and use claims 22 and 23 without undue experimentation.

The Patent Office suggests that not every conservative substitution in a peptide could be predicted to have the desirable activity. This is not a legally proper standard of nonenablement. The decision of *Atlas Powder Co. v. E.I. Du Pont De Nemours* makes clear that it is not the function of the claims to specifically exclude possible inoperative substances. (*See* 224 U.S.P.Q. 409, 414 (Fed. Cir. 1984)). Only “if the number of inoperative combinations become significant, and in effect forces one of ordinary skill in the art to experiment unduly in order to practice the claimed invention, the claims might indeed be invalid.” (*See id.*). Again, the specification teaches that the desired function can be achieved using SEQ ID NO: 1 and provides guidance to those of skill on making the appropriate conservative mutations. The Patent Office has presented no evidence that the instant specification does not enable claims 22 and 23.

For these reasons, Applicants respectfully submit that claims 22 and 23 are fully enabled pursuant to 35 U.S.C. § 112, first paragraph.

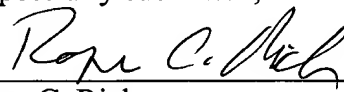
### CONCLUSION

In light of the above amendments and remarks, the Applicant respectfully requests that the Patent Office reconsider this application with a view towards allowance.

No fees, other than those for an extension of time, are believed to be due with this Amendment and Response. However, the Commissioner is authorized to charge all required fees, fees under 37 C.F.R. §1.17 and all required extension of time fees, or credit any overpayment, to Jones Day Deposit Account No. 503013 (Order No. 8907-091-999).

Respectfully submitted,

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